IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: IMPELLIZZERI, Frederic

SERIAL NO.: 10/530,683 ART UNIT: 3733

FILED: September 02, 2005 EXAMINER: Kim, John

TITLE: SELF-LOCKING OSTEOSYNTHESIS DEVICE

AMENDMENT "A"

Director of the U.S. Patent
and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action of April 24, 2006, a response being due with a one-month extension of time by August 24, 2006, please enter the present amendments and consider the following remarks:

REMARKS

Upon entry of the present amendments, previous Claims 1 - 9 have been canceled and new Claims 10 - 18 substituted therefor. Reconsideration of the rejections, in light of the forgoing amendments and present remarks, is respectfully requested. The present amendments have been entered for the purpose of distinguishing the present invention from the prior art and also for the purpose of placing the claim language into a more proper U.S. format.

In the Office Action, it was indicated that Claims 1 - 6 and 8 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Wolter patent. Claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Wolter patent in view of the Michaelson patent. Claims 1 -

9 were also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The specification was objected to because of minor informalities.

As an overview to the present reply, Applicant has extensively amended the original claim language in the form of new Claims 10 - 18. New Claims 10 - 18 express the original limitations of Claims 1 - 9 in a more proper U.S. format, respectively, including proper antecedent bases and proper structural interrelationships throughout. Any indefinite terminology found in the original claim language has been corrected herein.

In particular, in new independent Claim 10, Applicant has used the terms "openings" and "holes" so as to distinguish the "openings" that are formed in the plate and the "holes" that are formed into the inserts (which are "inserted" into the openings). Independent Claim 10 specifies that the plate is formed of a metallic material and that the plurality of inserts are formed of a biocompatible polymeric material. Independent Claim 10 further recites that the inserts are locked into the openings when a tapping screw is inserted into the hole. Applicant respectfully contends that these features serve the distinguish the present invention from the prior art.

It is important to note that the present invention places the polymeric inserts into the openings of the plate. This accomplishes two purposes. First, the use of the polymeric material facilitates the ability to insert a self-tapping screw into the hole of the insert. Since each of the screws has a threading, the use of such polymeric material allows the screw to "self-tap" instead of requiring that the metallic material have corresponding threads formed thereon. Secondly, because of the nature of the polymeric material, when a screw is inserted into the hole and self-tapped therein, the outer walls of the insert will expand so as to securely engage the walls of the openings of the metal plate. The importance of this feature was recited in paragraph [0035] of the original specification as

follows:

> However, in a preferred manner, the implementation of the inserts with PEEK 4 into the holes 6 of the metal plate 5 is done by means of a mechanical assembly. The inserts made of PEEK 4 are engaged, by deformation and pressure in the holes of the metal plate and are then held in these holes. For example, the inserts 4 can comprise a peripheral groove 4a in which an upper edge 6a of the holes 6 of the plate 1 come to engage, while the inserts are pushed into the holes. When the screws 3 are screwed in, the inserts 4 deform and are compressed between the edges of the holes 6 of the metal plate 5, which contributes to the solidity of the anchorage of these inserts in the metal plate.

As such, the present invention facilitates the locking of the inserts onto the plate and also facilitates the use of "self-tapping" screws. These features are neither shown nor suggested by the prior art Wolter patent.

The Wolter patent discloses a plate with holes 9, inserts 11 and tapping screws 1. In contrast to the analysis by the Examiner, the holes 9 of the plate (connection carrier 10) of the Wolter system are not made into inserts that are inserted into the openings made in the actual plate 10. The holes 9, in the Wolter patent, are formed directly in the plate. The "inserts" (11), as described by the Examiner, are simply a seating surface 11 obtained by machining the plate. These are not inserts that are placed into the plate. Quite clearly, there are no "plurality of inserts respectively received in said plurality of openings". Additionally, there is no suggestion in the Wolter patent that these inserts are formed of a biocompatible polymer material.

Applicant respectfully disagrees with the Examiner's analysis that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to have inserts made of plastic biocompatible material (high-performance thermoplastic or polyether ether ketone), since it is held to be within the general skill of a working in the art to select a known material on the

basis of its suitability for an intended use as a matter of obvious design choice." Since the Wolter patent does not describe a plate provided with such inserts, there is no reason to believe that a person having a skill in the art will create a composite osteosynthesis plate having a metal plate with inserts formed of plastic material. If this were the case, then the Wolter patent would not suggest the need for screw threads formed on the plate. The Wolter device is a plate made entirely of metal. Fundamentally, there is no teaching in the Wolter patent that, by placing these inserts into the opening, one could use "self-tapping" screws which, additionally, enhance the connection the outer walls of the insert and the inner walls of the openings. As such, the Wolter patent fails to suggest the function and advantages achieved by the positioning of these inserts into the respective openings on the plate.

Relative to dependent Claim 17, Applicant respectfully contends that the Wolter patent shows a screw having a threaded portion located below a smooth semi-spherical head. There is no "conical head" extending from the end of the screw. There is no "conical threading" extending from the end of the screw. In the Wolter patent, the head of the screw is illustrated as being smooth and semi-spherical. As such, the Wolter patent fails to teach the limitations shown in dependent Claim 17 (corresponding to original dependent Claim 8).

It should be noted that dependent Claim 17 also includes the statement that the conical threading engages "a wall of the hole of the insert such that the insert is in interference-fit relation with a wall of the opening. These features are neither shown nor suggested in any of the prior art patents.

Applicant has revised the specification in accordance with the Examiner's suggestions.

Based upon the foregoing analysis, Applicant contends that independent Claim 10 is now in

proper condition for allowance. Additionally, those claims which are dependent upon Claim 10 should also be in condition for allowance. Reconsideration of the rejections and allowance of the claims at an early date is earnestly solicited. Since no new claims have been added above those originally paid for, no additional fee is required.

Respectfully submitted,

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Date

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